Lhereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents, P.O. Box 1450

Alexandria, VA 22313 on the date shown below:

David R. Saliwanchik, Patent Attorney

INFORMATION DISCLOSURE STATEMENT Patent Application Docket No. IXN-100C1XCD2 Serial No. 10/671,299

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit

1632

Applicant(s)

Milton J. Allison, Harmeet Sidhu

Serial No.

10/671,299

Filed

September 24, 2002

For

Materials and Methods for Treating or Preventing Oxalate-Related Disease

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.97 and §1.98(d), the applicants would like to bring to the attention of the Examiner, the references cited in the following patent applications:

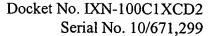
U.S. Serial No. 10/093,686, filed March 8, 2002 (pending);

U.S. Serial No. 09/083,362, filed May 22, 1998 (now U.S. Patent No. 6,200,562); and

U.S. Serial No. 09/500,500, filed February 9, 2000 (now U.S. Patent No. 6,355,242).

The subject application, Serial No. 10/671,299 claims the benefit under 35 USC §120 of the filing dates of the above applications (U.S. Serial Nos.09/083,362; 09/500,500; and 10/093,686). The applicants respectfully request that the copies of references supplied in the Information Disclosure Statement of the above-mentioned applications, as well as the references cited during





2



prosecution thereof, be made of record in the 10/671,299 application. As copies of the references filed in the parent applications, and cited on the attached form PTO-1449, will be found in the parent casefiles, copies of those references are not provided herewith.

It is respectfully requested that the references cited in the above-noted parent applications be considered in the examination of the subject application and their consideration be made of record.

Applicants respectfully assert that the substantive provisions of 37 CFR 001.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

David Saliwan kik

David R. Saliwanchik

Patent Attorney

Registration No. 31,794

Phone No.: 352-375-8100

Address: 2421 N.W. 41st Street, Suite A-1

Gainesville, FL 32606-6669

DRS/la

Enclosure: Form PTO-1449

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DESubstitute for form 1449A/PTO Complete if Known **Application Number** 10/671,299 INFORMATION DISCLOSURE Filing Date September 24, 2003 STATEMENT BY APPLICANT First Named Inventor Milton J. Allison (use as many sheets as necessary) **Art Unit** 1632 **Examiner Name** Sheet of 2 **Attorney Docket Number** 1 IXN-100C1XCD2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
_	U1	US-5,286,495	02-15-1994	Batich et al.	
	U2	US-5,547,870	08-20-1996	Datta et al.	<u> </u>
	U3	US-5,604,111	02-18-1997	Peck	
	U4	US-6,200,562	03-13-2001	Allison et al.	
	U5	US-6,355,242	03-12-2002	Allison et al.	
	U6	US-			
	U7	US-			
	U8	US-			E
	U9	US-	1		
	U10	US-			
	U11	US-			
	U12	US-			
	U13	US-			
	U14	US-	1		
	U15	US-			<u> </u>
	U16	US-			
	U17	US-	Ī .		
	U18	US-			
	U19	US-			***************************************
	U20	US-			

FOREIGN PATENT DOCUMENTS						
	I	Foreign Patent Document			Pages, Columns, Lines,	
Examiner Initials*	Cite No. <sup>1</sup>	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T⁵
	F1	WO 95/31537	11-23-1995			
	F2	WO 95/35377	12-28-1995			
	F3	WO 98/16632				
	F4					
	F5					
	F6					
	F7					
	F8					
	F9					
	F10					

Examiner	Date
Signature	Considered

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁵ Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B (10-01)

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

control. Under the Pa aperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

2

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

2

of

Sheet

Complete if Known			
Application Number	10/671,299		
Filing Date	September 24, 2003		
First Named Inventor	Milton J. Allison		
Group Art Unit	1632		
Examiner Name			
Attorney Docket Number	IXN-100C1XCD2		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
	R1	Allison, M.J., H.M. Cook (1981) "Oxalate degradation by microbes of the large bowel of herbivores: the effect of dietary oxalate" Science 212:675-676.	
	R2	Allison, Milton J., Karl A. Dawson, William R. Mayberry, John G. Foss (1985) "Oxalobacter formigens gen. nov., sp. now.: oxalate-degrading anaerobes that inhibit the gastrointestinal tract" Arch Microbiol 141:1-7.	
	R3	Allison, Milton J., Herbert M. Cook, David B. Milne, Sandra Gallagher, Ralph V. Clayman (1986) "Oxalate Degradation by Gastrointestinal Bacteria from Humans" J. Nutr. 116:455-460.	
	R4	Allison, Milton J., Steven L. Daniel, Nancy A. Cornick (1995) "Oxalate-Degrading Bacteria" In: Khan, S.R. (ed), Calcium Oxalate in Biological Systems CRC Press, Chapter 7, pp 131-168.	
	R5	Daniel, S.L., P.A. Hartman, M.J. Allison (1993) "Intestinal Colonisation of Laboratory Rats by Anaerobic Oxalate-degrading Bacteria: Effects on the Urinary and Faecal Excretion of Dietary Oxalate" Microbial Ecology in Health and Disease 6:277-283.	
	R6	Daniel, Steven L., Paul A. Hartman, Milton J. Allison (1987) "Microbial Degradation of Oxalate in the Gastrointestinal Tracts of Rats" Applied and Environmental Microbiology 53(8):1793-1797.	
	R7	Dawson, Karl A., M.J. Allison, P.A. Hartman (1980) "Isolation and Some Characteristics of Anaerobic Oxalate- Degrading Bacteria from the Rumen" Applied and Environmental Microbiology 40(4):833-839.	
	R8	Doane, Lori T., Michael Liebman, Daniel R. Caldwell (1989) "Microbial Oxalate Degradation: Effects On Oxalate And Calcium Balance In Humans" Nutrition Research 9:957-964.	
	R9	Han, Jian-zhi et al. (1995) "The Relationship of Oxalobacter Formigenes and Calcium Oxalate Calculi" Journal of Tongji Medical University 15(4):249-252.	
	R10	Ito, Haruo, Masami Miyake, Masatoshi Noda (1995) "A New Oxalate-degrading Organism Isolated from Human Feces" Abstr. Annual Meeting Amer. Soc. Microbiol. Q-106.	
	R11	Jensen, Neil S., Milton J. Allison (1994) "Studies on the Diversity Among Anaerobic Oxalate Degrading Bacteria now in the Species Oxalobacter formigenes" Abstr. General Meeting of the American Soc. Microbiol. I-12.	
	R12	Lung, Hui-Yu et al. (1991) Cloning and expression of the oxalyl-CoA decarboxylase gene from the bacterium, Oxalobacter formigenes: prospects for gene therapy to control Ca-oxalate kidney stone formation" American Journal of Kidney Disease Vo.I. XVII (4): 381-385.	
	R13	Sidhu, H., M.J. Allison, A.B. Peck (1996) "Detection and Characterization of Oxalobacter formigenes Strains Using Oligonucleotide Probes" Meeting for Urolithaisis, pp 537-539, Pak, C.Y.C. et al. (ed.).	
	R14	Solomons, Clive C., M. Herzl Melmed, Susan M. Heitler (1991) "Calcium Citrate For Vulvar Vestibulitis" The Journal of Reproductive Medicine 36(12):879-882.	

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.